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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,668	02/25/2002	Jorg Breitenbach	480/1240	8161

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EXAMINER	
BENNETT, RACHEL M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,668	BREITENBACH ET AL.	
	Examiner	Art Unit	
	Rachel M. Bennett	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The examiner acknowledges receipt of the amendment filed 11/5/03.

Specification

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breitenbach et al. (US 6221638 B1).

Applicants claim a solid formulation comprising 10-30% lipoid acid and where appropriate, other active substances and a formulation base having a binder component and where appropriate other excipients, wherein lipoid acid is in the form of a molecular dispersion.

Breitenbach discloses a process for producing solid dose forms by mixing at least one polymeric binder, with or without at least one active ingredient and with or without conventional additives, and shaping the mixture, where at least one of the components is employed in liquid form. See abstract. The dose forms obtainable generally comprise: a) from 0 to 100% by weight, in particular from 0.1 to 50% by weight of an active ingredient, b) from 0 to 100% by weight in particular from 50 to 99.9% by weight of a polymeric binder and c) with or without additives. Particularly suitable binders are pharmacologically acceptable polymers. See col. 2 lines 13-39. The polymeric binder is preferably employed in the form of an aqueous or alcoholic dispersion or solution. See col. 2 lines 40-48. The dispersions are preferably prepared using

physiologically tolerated emulsifiers or protective colloids as dispersants. Examples include cellulose derivatives, polyvinylpyrrolidone or copolymers containing vinylpyrrolidone. Further useful binders include cellulose derivatives such as cellulose esters and cellulose ethers. See col. 4. The amount of active ingredient per dose unit and the concentration can each be varied within wide limits depending on efficacy and rate of release. The sole condition is that they are sufficient to attain the desired effect. Thus, the concentration of active ingredient can be in particular in the range from 0.1 to 95, preferably from 20-80 and especially from 30 to 70% by weight. Combinations of active ingredients can also be employed. Active ingredients can be vitamins and mineral substances. The vitamins include vitamins of the A group, and the B group, including lipoic acid. See col. 6, lines 38-58. Breitenbach does not specifically disclose lipoic acid in a specific example

Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used lipoic acid the solid dosage form taught by Breitenbach because Breitenbach teaches lipoic acid may be used as the active ingredient. Furthermore, Breitenbach also teaches lipoic acid may be used in combination with other active ingredients.

Response to Arguments

3. Applicant's arguments filed 11/5/03 have been fully considered but they are not persuasive.

Applicants argue that although Breitenbach discloses lipoic acid in a very broad listing of active ingredients it is not mentioned anywhere else in the reference. Applicants also argue on of ordinary skill in the art could have had no reasonable expectation of producing solid

compositions containing the levels of lipoic acid recited in the claims as amended. The examiner refers to Breitenbach wherein Breitenbach discloses a process for producing solid dose forms by mixing at least one polymeric binder, with or without at least one active ingredient and with or without conventional additives, and shaping the mixture, where at least one of the components is employed in liquid form. The dose forms obtainable generally comprise: a) from 0 to 100% by weight, in particular from 0.1 to 50% by weight of an active ingredient, b) from 0 to 100% by weight in particular from 50 to 99.9% by weight of a polymeric binder and c) with or without additives. Breitenbach further discloses the amount of active ingredient per dose unit and the concentration can each be varied within wide limits depending on efficacy and rate of release. The sole condition is that they are sufficient to attain the desired effect. Thus, the concentration of active ingredient can be in particular in the range from 0.1 to 95, preferably from 20-80 and especially from 30 to 70% by weight. Therefore, it is the position of the examiner that Breitenbach discloses a solid dose form comprising an active ingredient, lipoic acid, preferably in the range from 20-80% by weight of the composition. The rejection is maintained.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779 (after 2/4/04 (571) 272-0589). The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927 (after 2/4/04 (571-272). The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600